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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,690	SOUKKA ET AL.	
	Examiner	Art Unit	
	MELANIE YU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-38* is/are pending in the application.

4a) Of the above claim(s) *14-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 14-25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions of a) claims 14-25 and b) claims 26-38 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nanoparticle of claims 26-38 can be used in a materially different process such as separation and filtration of analyte from a sample.

Since applicant has received an action on the merits for the originally presented invention of a nanoparticle which is encompassed by claims 26-38, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 14-25 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 26-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification fails to teach genetically fused first and second binding moieties and the shell of a nanoparticle being a recombinant Dpr/Dps protein particle. It is noted that the instant specification teaches fusing genes to form a conjugate between a binding molecule and a marker protein at (pg. 3, second paragraph) and also teach E-coli cells expressing plasmids encoding a binding molecule fused to N-terminus of ferritin (example 1). However, nowhere in the instant specification is support provided for binding moieties that are "genetically fused". It is also noted that the specification, at page 1, fourth paragraph, the instant specification teaches a Dpr protein and a Dps protein in the prior art, but the specification does not teach or provide support for a recombinant Dpr/Dps protein particle as recited in claim 26.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 26-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites "one or several genetically fused first binding moieties" and "one or several genetically fused second binding moieties" in parts a and b of the claim, respectively and claim 31 recites "one or several third genetically fused binding moieties". Applicant does not provide a definition or arguments for the meaning of

"genetically fused" so it is unclear what is meant by "genetically fused". It is vague as to whether the binding moiety is intended to be a gene, whether the binding moiety and subunit are fused genes, or whether the binding moieties is produced by gene fusion. The claim is interpreted as being a binding moiety that is produced by gene fusion.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 26, 27, 29 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Kameda et al. (US 4,959,306).

Kameda et al. teach a nanoparticle comprising a self-assembling shell built up of several protein subunits of one type (apoferritin contains 24 protein subunits and is arranged as a spherical shell, which is a particle, col. 8, lines 65-67, although Kameda et al. do not specifically recite the particle being a nanoparticle, the particle is the same type, apoferritin, as that described in the instant specification and is therefore also a nanoparticle) assembled in an organized manner to form the shell having an inner surface facing the inside and an outer shell facing the outside of the particle (iron is removed from ferritin, which indicates that a portion of the apoferritin faces the inside of the shell and an outer portion faces the outside of the particle, col. 10, lines 38-48) wherein one of the types of subunits have a first binding moiety facing the outside of the particle for binding of any specific ligand binding protein (linkers specific to ferritin

conjugated to apoferritin, col. 10, lines 55-68); and the particle contains attached to a type of subunit having a second binding moiety for binding a marker (Fab' fragments are labeled with fluorescein and attached to the particle, col. 11, lines 1-32); and the marker enables detection of the particle (fluorescein is used for detection, col. 11, lines 49-52) wherein the shell of the nanoparticle is an apoferritin-like particle (col. 8, lines 65-67). Although Kameda et al. do not specifically teach a genetically fused first binding moiety and a genetically fused second binding moiety, such a limitation is drawn to product by process. Since claim 26 is drawn to a nanoparticle, the prior art must teach the claimed final product and is not required to teach the same method of making the claimed product. Kameda et al. teach a first and second binding moiety and therefore reads on the same final product recited in claim 26. Kameda et al. also do not specifically teach a recombinant apoferritin particle, but teach an apoferritin particle made from a natural human liver ferritin (col. 10, lines 38-48). Therefore since the prior art teaches the same apoferritin particle as recited in the rejected claims, the apoferritin of Kameda et al. reads on the claimed final product of an apoferritin particle.

Regarding claim 27, Kameda et al. teach the first binding moiety fused to the N-terminus of the apoferritin protein (linkers are attached to the end of the apoferritin and therefore are fused to the N-terminus, col. 10, lines 55-68).

With respect to claim 29, Kameda et al. teach the marker being fluorescein (col. 11, lines 1-32).

Regarding claim 36, Kameda et al. teach an apoferritin that is produced from a human liver ferritin (col. 10, lines 38-48), but do not recite the size of the apoferritin.

However, the instant specification teaches an apoferritin produced from a human liver ferritin molecule in the background of the invention as having the necessary dimensions. Therefore, the apoferritin molecule

With respect to claim 37, Kameda et al. teach the number of subunits being 24 (col. 8, lines 65-67), which encompasses the recited range of more than 8.

Regarding claim 38, Kameda et al. teach the nanoparticle of claim 1 and therefore teach a kit comprising the particle.

5. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kameda et al. (US 4,959,306), as applied to claim 26, in view of Bertozzi et al. (US 6,713,274).

Kameda et al. teach an apoferritin nanoparticle having a fluorescent marker that is fluorescein, but fail to specifically teach the marker being a lanthanide.

Bertozzi et al. teach that a detectable fluorescent marker may alternatively be fluorescein, luciferase or a lanthanide that is ^{124}Eu (col. 10, lines 11-27), in order to provide a detectable label for detection of antibody binding.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute for the fluorescein marker taught by Kameda et al., a luciferase or lanthanide marker as taught by Bertozzi et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent labeling technique and since the same expected detection effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

6. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kameda et al. (US 4,959,306), as applied to claim 26, in view of Griffiths et al. (US 2003/0124586).

Kameda et al. teach an apoferritin having two types of binding moieties, but fail to teach a third type of binding moiety facing the outside of the particle for binding to a solid support.

Griffiths et al. teach a binding moiety facing the outside of an apoferritin for binding to a solid support (par. 239), in order to provide linkage of a probe and target analyte to a substrate for detection.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include on the apoferritin nanoparticle of Kameda et al., a third binding moiety facing the outside of the particle for binding to a solid support as taught by Griffiths et al., in order to provide detection of binding that is localized to a specific area.

7. Claims 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kameda et al. (US 4,959,306), as applied to claim 1, in view of Chandler et al. (US 6,599,331).

Kameda et al. teach a first and second binding moiety, but fail to teach the first binding moiety being protein A, protein G, protein L CBP or BCCP.

Chandler et al. teach that protein A is conjugated to a particle for attachment of a fluorescent label (col. 7, lines 42-65), in order to provide labeling or specific binding for a bead.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the first binding moiety of Kameda et al., a protein A conjugated to the particle as taught by Chandler et al., in order to provide sufficient and easy attachment of labels to the particle.

8. Claims 33, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kameda et al. (US 4,959,306), as applied to claim 26, in view of Bergmann et al. (US 6,537,760).

Kameda et al. teach the first and second binding moiety being an antibody against CRP, ABO blood group antigens and TSH.

Bergmann et al. teach an antibody against TSH as a first specific binding moiety or to bind a label (antibody to TSH is immobilized to a particle and binds to TSH to detect a labeled TSH, col. 9, lines 5-12), in order to provide accurate detection of TSH.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the first or second moiety of Kameda et al., an antibody to TSH as taught by Bergmann et al., in order to provide an accurate indicator with greater clinical value for TSH which is detected to diagnose Graves' disease.

With respect to claim 36, a nanoparticle having these binding moieties and an apoferritin shell is the same as that recited in the claims and would therefore have the same size and radius properties as those recited in claim 36. Therefore, according to the instant specification, the nanoparticle taught by Kameda et al. in view of Bergmann et al. has a radius that is between 10 and 40 nm.

9. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kameda et al. (US 4,959,306), as applied to claim 26, in view of Oon et al. (US 2003/0077578).

Kameda et al. teach a first and second binding moiety, but fail to teach the second binding moiety being protein A, protein G, protein L CBP or BCCP.

Oon et al. teach that protein A is conjugated to a support as a specific binding moiety (par. 96), in order to provide an antibody that binds immunoglobulins.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the first binding moiety of Kameda et al., a protein A conjugated to the particle as taught by McCormick et al., in order to separate any tagged target protein complexes from a sample for accurate detection.

Response to Arguments

10. Applicant's arguments filed 30 June 2008 have been fully considered but they are not persuasive. Applicant argues that Kameda et al. and the other references of record fail to teach a recombinant apoferritin particle. Applicant's arguments are not persuasive because such a limitation is drawn to a product by process. Since the claims are drawn to a product, the prior art must only teach the final product. The method of making the product is not given patentable weight so long as the final products are the same. The apoferritin taught by Kameda et al. is made from a human liver ferritin particle and therefore results in the same product as an apoferritin particle made by a recombinant process. Therefore, since Kameda et al. teach the same resulting apoferritin particle, the final products are the same.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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